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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/677,752	10/03/2000	W. James Jackson	7969-087	5261

20583 7590 02/12/2003

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EXAMINER
FORD, VANESSA L

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 02/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/677,752	JACKSON, W. JAMES	
	Examiner	Art Unit	
	Vanessa L. Ford	1645	

-- The MAILING DATE of this communication app ars on the cover sheet with the correspondenc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 November 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *42-49 and 79-106* is/are pending in the application.

4a) Of the above claim(s) *42-49* is/are withdrawn from consideration.

5)☒ Claim(s) *94 and 95* is/are allowed.

6)☒ Claim(s) *79-93 and 96-106* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *13* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 5, 2002 has been entered.

2. Applicant's amendment filed November 5, 2002 is acknowledged. Claims 1-4, 6-7, 15-24, 31-32, 41, 57-59 and 73-78 have been cancelled. Claims 79-106 have been added. Claims 42-49 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being to a non-elected invention. It should be noted that Applicant's amendment refers to Exhibits 1-17, however, Exhibits 1-17 were not received and are not in the file with Applicant's amendment. Due to a typographical error in the previous Office action (paper no. 12), paragraphs 10 and 11, the rejection of claims 57-59 and 73-74 as anticipated by Longbottom et al and the rejection of claims 57-59 and 73-74 as anticipated by Stephens et al respectively, should have been rejected under 35 U.S.C. 102(b) instead of 102(e). The Office apologizes for the oversight.

3. The text of those sections of the Title 35, U.S. code not included in this action can be found in the prior Office Action.

Rejections Withdrawn

4. In view of Applicant's amendment the following objections and rejections are withdrawn:

a) Rejection of claims 1-4 and 6 under 35 U.S.C. 102(b), pages 5-6, paragraph 6 of the previous Office action.
b) Rejection of claims 1-2 and 4 under 35 U.S.C. 102(b), pages 7-8, paragraph 7 of the previous Office action.
c) Rejection of claims 1 and 6 under 35 U.S.C. 102(e), pages 8-9, paragraph 8 of the previous Office action.
d) Rejection of claims 1, 15-24, 41 and 75-76 under 35 U.S.C. 102(e), pages 9-10, paragraph 9 of the previous Office action.
e) Rejection of claims 57-59 and 73-74 under 35 U.S.C. 102(e), pages 11-12, paragraph 10 of the previous Office action.
f) Rejection of claims 57-59 and 73-74 under 35 U.S.C. 102(e), pages 12-14, paragraph 11 of the previous Office action.
g) Rejection of claims 1, 31-32 and 77-78 under 35 U.S.C. 103(a), pages 14-16, paragraph 12 of the previous Office action.
h) Rejection of claim 74 under 35 U.S.C. 103 (a), pages 16-18, paragraph 13 of the previous Office action.

Rejections Maintained

5. The rejection of under 35 U.S.C. 112, first paragraph is maintained for 79-93 and 96-106 for reasons set forth on pages 3-5, paragraph 5 of the previous Office Action.

The rejection was on the grounds that the claims are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification discloses SEQ ID NO: 2 or 4 which corresponds to the amino acid sequence that encodes a PMPE or PMPI polypeptide. Claims 1-7 are directed to sequences that are substantially homologous to SEQ ID NO: 2 or 4, corresponding sequences from other species, mutated sequences, allelic variants, splice variants, sequences that have a variant degree of identity (similarity, homology), and so forth. The specification provides insufficient written description to support the genus encompassed by the claim.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought,

he or she was in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)
With the exception of SEQ ID NO:2 or 4, the skilled artisan cannot envision the detailed chemical structure of the encompassed polypeptide regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

Therefore, only SEQ ID NO: 2 or 4 but not the full breadth of the claim (or none of the sequences encompassed by the claim) meets the written description provision of 35 USC 112, first paragraph. The species specifically disclosed are not representative of the genus because the genus is highly variant. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. (See page 1115.)

Applicant urges that the specification fully discloses at least two full length PMPE proteins, (i.e. two species of the claimed genus). Applicant urges that specification discloses PMPE polypeptides comprising PMPE protein fused to an affinity purification tag which is a species of the genus. Applicant urges that numerous fragments of PMPE are disclosed in Table I, page 18 of the specification. Applicant urges that the specification discloses chimeric polypeptides comprising PMPE polypeptides fused to heterologous sequences including chimeric polypeptides, Hin47, PMPE, HWMP or PMPE and MOMP. Applicant urges that the specification discloses that PMPE proteins can be used in fusion proteins comprising the B subunit of cholera toxin, the B subunit of *E. coli* heat labile toxin, IL2, II4, IL-10, IL-12 and interferon. Applicant urges that the specification teaches one skilled in the art to make and use all claimed PMPE proteins and fragments thereof. Applicant urges that the claims are

drawn to vaccine compositions containing isolated PMPE proteins which bind to an antibody that specifically binds to SEQ ID NO:2 and SEQ ID NO: 2 is an example of a full length PMPE protein. Applicants urges that the isolated full length PMPE protein is efficacious in inducing a protective (immune) antibody response for ameliorating disease associated with Chlamydial infection. Applicant urges that once it is known that a particular protein is efficacious in inducing a protective immune response for ameliorating a disease, it is routine to screen protein variants or fragments for the ability to bind to antigen specific antibodies. Applicant refers to Deslauriers et al, 1996, Sexton et al, 1994, Briles et al, U.S. Patent NO. 5,964,141, Carlson et al, 1997, Nilsson et al, 1998, Charles et al, U.S. Patent No. 5,976,544 to demonstrate that one skilled in the art would have had an expectation that fragments or analogs of proteins which react to an antibody that binds to SEQ ID NO:2 would retain ability to induce a protective immune response and would be able to determine without undue experimentation whether a particular peptide or variant of PMPE retained the ability to elicit a protective immune response.

Applicant's arguments filed November 5, 2002 have been fully considered but they are not persuasive. It is the Examiner's position that there is nothing on the record to that the specification is enabled for the full scope of the claims and therefore does not meet the written description requirement as set forth in 35 U.S.C. 112, first paragraph. The specification broadly describes a genus of isolated polypeptides. Applicant has provided no structural description accompanying the variant language (i.e. polypeptides that have a molecular weight between 90 and 115 kDa and specifically binds an

antibody that specifically binds a protein comprising the amino acid of SEQ ID NO:2 or a PMPE polypeptides that comprise an amino acid sequence that is at least 70% identical to SEQ ID NO:2 or a polypeptide comprising at least an 8 amino acid fragment of SEQ ID NO:2 which specifically binds an antibody that specifically binds to a protein comprising the amino acid of SEQ ID NO:2) recited in the claims. Although the specification has disclosed full length PMPE proteins and discloses several fragments of the PMPI protein, it is not routine in the art to screen for multiple substitutions or multiple modifications of other types and the positions within the polypeptide where amino acid modifications can be made with a reasonable expectation of success in obtaining similar activity are limited in any polypeptide and the result of such modifications is unpredictable based on the instant disclosure. There is no guidance provided in the specification as how one would begin to choose "a polypeptide fragment comprising at least 8 amino acids that specifically bind to an antibody that specifically binds to a protein comprising the amino acid sequence of SEQ ID NO:2".

Applicant's comments regarding the Deslauriers et al, Sexton et al, Briles et al, Carlson et al, Nilsson et al references are not addressed because the references were not submitted with Applicant's amendment and have not been considered (see paragraph 1).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 91-93 are rejected under 35 USC 112 second paragraph for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 91-93 recite "under conditions suitable", it is unclear as to what the Applicant is referring? Clarification is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

7. Claims 79-89 and 96-105 are rejected under 35 U.S.C. 102(b) as anticipated by Graffais et al *(WO 9928474, published June 10, 1999).*

Claims 79-89 and 96-105 are drawn to a vaccine comprising an isolated putative membrane protein E (PMPE) polypeptide of a *Chlamydia spp.* having a molecular weight between 90 and 115 kDa as determined by SDS polyacrylamide gel electrophoresis which protein specifically binds an antibody that specifically binds to a protein comprising the amino acid of SEQ ID NO:2 and a pharmaceutically acceptable carrier or diluent.

Griffais et al teach polypeptides from *Chlamydia trachomatis* that can be used in vaccines for the prevention and/or treatment of *Chlamydia trachomatis* infections (see the Abstract). Griffais et al teach that vaccines of the invention contain a pharmaceutically acceptable vehicle and may contain adjuvants (page 76). Griffais et al teach a polypeptide (SEQ ID NO: 31) that is 99.2% identical to the claimed polypeptide disclosed in SEQ ID NO:2. Therefore the polypeptide of the prior art can specifically bind to an antibody that specifically binds to a protein comprising the amino acid of SEQ ID NO:2. See enclosed sequence alignment.

Since the Office does not have the facilities for examining and comparing applicant's vaccine and peptide fragment with the vaccine and peptide fragment of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the vaccine and peptide fragment of the prior art does not possess the same material structural and functional characteristics of the claimed vaccine and peptide fragment). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

8. Claims 79-89 and 96-105 are rejected under 35 U.S.C. 102(a) as anticipated by Probst et al *(WO 00/34483, published June 15, 2000).*

Claims 79-89 and 96-105 are drawn to a vaccine comprising an isolated putative membrane protein E (PMPE) polypeptide of a *Chlamydia spp.* having a molecular weight between 90 and 115 kDa as determined by SDS polyacrylamide gel electrophoresis which protein specifically binds an antibody that specifically binds to a protein comprising the amino acid of SEQ ID NO:2 and a pharmaceutically acceptable carrier or diluent.

Probst et al teach pharmaceutical compositions and vaccines comprising Chlamydial polypeptides (see the Abstract). Probst et al teach vaccines comprising antibodies (page 58 and page102, claim 22). Probst et al teach that the vaccines of the invention may comprise one or more polypeptide and an immunostimulant (pages 45-46). Probst et al teach that any variety of immunostimulants may be employed in the vaccine compositions of the invention and an adjuvant may be included (page 47). Probst et al teach that the vaccine may include a combination of adjuvants such as monophosphoryl lipid A (MPL) and saponin (QS21) (pages 48-49). Probst et al teach that any vaccine provided in the invention may include a combination of antigen, immune response enhancer and a suitable carrier or excipient (page 49). Probst et al teach that vaccines of the invention may also contain other *Chlamydia* antigens either incorporated into a combination polypeptide or present within a separate polypeptide (page 42). Probst et al teach SEQ ID NO:177 which is the predicted full-length amino acid sequence for *C. trachomatis* (page 17). Probst et al teach a polypeptide (SEQ ID

NO: 177) that is 98% identical to SEQ ID NO:2 and comprises the claimed peptide fragment of SEQ ID NO: 5. See enclosed sequence alignment.

Since the Office does not have the facilities for examining and comparing applicant's vaccine and peptide fragment with the vaccine and peptide fragment of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the vaccine and peptide fragment of the prior art does not possess the same material structural and functional characteristics of the claimed vaccine and peptide fragment). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

9. Claims 79-89 and 96-105 are rejected under 35 U.S.C. 102(e) as anticipated by Probst et al *(U.S. Patent No. 6,432,916, published August 13, 2002).*

Claims 79-89 and 96-105 are drawn to a vaccine comprising an isolated putative membrane protein E (PMPE) polypeptide of a *Chlamydia spp*. Having a molecular weight between 90 and 115 kDa as determined by SDS polyacrylamide gel electrophoresis which protein specifically binds an antibody that specifically binds to a protein comprising the amino acid of SEQ ID NO:2 and a pharmaceutically acceptable carrier or diluent.

Probst et al teach pharmaceutical compositions and vaccines comprising Chlamydial polypeptides (see the Abstract). Probst et al teach that the vaccines of the invention may comprise one or more polypeptide and an immunostimulant (column 27). Probst et al teach that any variety of immunostimulants may be employed in the vaccine

compositions of the invention and an adjuvant may be included (column 27). Probst et al teach that the vaccine may include on or more immunostimulants (column 30). Probst et al teach that any vaccine provided in the invention may include a combination of antigen, immune response enhancer and a suitable carrier or excipient (column 27). Probst et al teach that vaccines of the invention may also contain other *Chlamydia* antigens either incorporated into a combination polypeptide or present within a separate polypeptide (column 27). Probst et al teach SEQ ID NO:177 which is the predicted full-length amino acid sequence for *C. trachomatis* (column 10). Probst et al teach a polypeptide (SEQ ID NO: 177) that is 98% identical to SEQ ID NO:2 and comprises the claimed peptide fragment of SEQ ID NO: 5. See enclosed sequence alignment.

Since the Office does not have the facilities for examining and comparing applicant's vaccine and peptide fragment with the vaccine and peptide fragment of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the vaccine and peptide fragment of the prior art does not possess the same material structural and functional characteristics of the claimed vaccine and peptide fragment). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Please note: The Examiner is viewing claim 91-93 as a product by process claim. The Examiner is viewing claims 91-93 to read on a genus of isolated recombinant PMPE polypeptides that are produced by a method comprising culturing a host cell containing a nucleic acid molecule comprising SEQ ID NO:1. The scope of claims 91-93 encompasses PMPE polypeptides from *Chlamydia trachomatis*, *Chlamydia pneumonia*, *Chlamydia psittaci* and *Chlamydia pecorum* (specification pages 11 and 24). The Examiner is also viewing the "recombinant PMPE polypeptides" to have the same characteristics as the native PMPE polypeptides.

10. Claims 91-93 are rejected under 35 U.S.C. 102(b) as anticipated by Graffais et al *(WO 9928474, published June 10, 1999).*

Claims 91-93 are drawn to a vaccine comprising an isolated recombinant PMPE polypeptide produced by a method comprising culturing a host cell containing a nucleic acid molecule comprising the nucleic acid sequence of SEQ ID No:1 fused to a nucleotide sequence encoding a histidine affinity ($(H6)_6$) domain under conditions suitable for expression of said PMPE polypeptide and recovering said recombinant PMPE polypeptide and a pharmaceutically acceptable carrier or diluent.

Griffais et al teach polypeptides from *Chlamydia trachomatis* that can be used in vaccines for the prevention and or treatment of *Chlamydia trachomatis* infections (see the Abstract). Griffais et al teach that vaccines of the invention contain a pharmaceutically acceptable vehicle and may contain adjuvants (page 76). Griffais et al teach a polypeptide (SEQ ID NO: 31) that is 99.2% identical to the claimed polypeptide disclosed in SEQ ID NO:2. Therefore the polypeptide of the prior art, can specifically bind to an antibody that specifically binds to a protein comprising the amino acid of SEQ ID NO:2. See enclosed sequence alignment.

Although the reference appears to disclose vaccines comprising the same purified polypeptides claimed by the applicant's, the reference does not disclose that the purified polypeptides produced by the same claimed process. However, the purification or production of protein by a particular process does not impart novelty or unobviousness to a protein when the same protein is taught by the prior art. This is particularly true when the properties of the protein are not changed by the process in an

unexpected manner. See In re Thorpe, 227 USPQ 964 (CAFC 1985); In re Marsosi, 218 USPQ 289, 292-293 (CAFC 1983); In re Brown, 173 USPQ 685 (CCPA 1972).

Since the Office does not have the facilities for examining and comparing applicant's vaccine and peptide fragment with the vaccine and peptide fragment of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the vaccine and peptide fragment of the prior art does not possess the same material structural and functional characteristics of the claimed vaccine and peptide fragment). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

11. Claims 91-93 are rejected under 35 U.S.C. 102(a) as anticipated by Probst et al *(WO 00/34483, published June 15, 2000).*

Claims 91-93 are drawn to a vaccine comprising an isolated recombinant PMPE polypeptide produced by a method comprising culturing a host cell containing a nucleic acid molecule comprising the nucleic acid sequence of SEQ ID No:1 fused to a nucleotide sequence encoding a histidine affinity ($(H6)_6$) domain under conditions suitable for expression of said PMPE polypeptide and recovering said recombinant PMPE polypeptide and a pharmaceutically acceptable carrier or diluent.

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vaccine compositions of the invention and an adjuvant may be included (page 47). Probst et al teach that the vaccine may include a combination of adjuvants such as monophosphoryl lipid A (MPL) and saponin (QS21) (pages 48-49). Probst et al teach that any vaccine provided in the invention may include a combination of antigen, immune response enhancer and a suitable carrier or excipient (page 49). Probst et al teach SEQ ID NO:177 which is the predicted full-length amino acid sequence for *C. trachomatis* (page 17). Probst et al teach a polypeptide (SEQ ID NO: 177) that is 98% identical to SEQ ID NO:2 and comprises the claimed peptide fragment of SEQ ID NO: 5. See enclosed sequence alignment.

Although the reference appears to disclose vaccines comprising the same purified polypeptides claimed by the applicant's, the reference does not disclose that the purified polypeptides produced by the same claimed process. However, the purification or production of protein by a particular process does not impart novelty or unobviousness to a protein when the same protein is taught by the prior art. This is particularly true when the properties of the protein are not changed by the process in an unexpected manner. See In re Thorpe, 227 USPQ 964 (CAFC 1985); In re Marsosi, 218 USPQ 289, 292-293 (CAFC 1983); In re Brown, 173 USPQ 685 (CCPA 1972).

Since the Office does not have the facilities for examining and comparing applicant's vaccine with the vaccine of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the vaccine of the prior art does not possess the same material

structural and functional characteristics of the claimed vaccine). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

12. Claims 91-93 are rejected under 35 U.S.C. 102(e) as anticipated by Probst et al *(U.S. Patent No. 6,432,916, published August 13, 2002).*

Claims 91-93 are drawn to a vaccine comprising an isolated recombinant PMPE polypeptide produced by a method comprising culturing a host cell containing a nucleic acid molecule comprising the nucleic acid sequence of SEQ ID No:1 fused to a nucleotide sequence encoding a histidine affinity ($(H6)_6$) domain under conditions suitable for expression of said PMPE polypeptide and recovering said recombinant PMPE polypeptide and a pharmaceutically acceptable carrier or diluent.

Probst et al teach pharmaceutical compositions and vaccines comprising Chlamydial polypeptides (see the Abstract). Probst et al teach that the vaccines of the invention may comprise one or more polypeptide and an immunostimulant (column 27). Probst et al teach that any variety of immunostimulants may be employed in the vaccine compositions of the invention and an adjuvant may be included (column 27). Probst et al teach that the vaccine may include on or more immunostimulants (column 30). Probst et al teach that any vaccine provided in the invention may include a combination of antigen, immune response enhancer and a suitable carrier or excipient (column 27). Probst et al teach that vaccines of the invention may also contain other *Chlamydia* antigens either incorporated into a combination polypeptide or present within a separate polypeptide (column 27). Probst et al teach SEQ ID NO:177 which is the predicted full-

length amino acid sequence for *C. trachomatis* (column 10). Probst et al teach a polypeptide (SEQ ID NO: 177) that is 98% identical to SEQ ID NO:2 and comprises the claimed peptide fragment of SEQ ID NO: 5. See enclosed sequence alignment.

Although the reference appears to disclose vaccines comprising the same purified polypeptides claimed by the applicant's, the reference does not disclose that the purified polypeptides produced by the same claimed process. However, the purification or production of protein by a particular process does not impart novelty or unobviousness to a protein when the same protein is taught by the prior art. This is particularly true when the properties of the protein are not changed by the process in an unexpected manner. See In re Thorpe, 227 USPQ 964 (CAFC 1985); In re Marsosi, 218 USPQ 289, 292-293 (CAFC 1983); In re Brown, 173 USPQ 685 (CCPA 1972).

Since the Office does not have the facilities for examining and comparing applicant's vaccine with the vaccine of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the vaccine of the prior art does not possess the same material structural and functional characteristics of the claimed vaccine). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

13. Claims 79-90 and 96-106 are rejected under 35 U.S.C. 103(a) as unpatentable over Probst *(U.S. Patent No. 6,432,916, published August 13, 2002)* in view of Murdin et al *(Infection and Immunity, October 1993, p. 4406-4414).*

Probst et al teach pharmaceutical compositions and vaccines comprising Chlamydial polypeptides (see the Abstract). Probst et al teach that the vaccines of the invention may comprise one or more polypeptide and an immunostimulant (column 27). Probst et al teach that any variety of immunostimulants may be employed in the vaccine compositions of the invention and an adjuvant may be included (column 27). Probst et al teach that the vaccine may include on or more immunostimulants (column 30). Probst et al teach that any vaccine provided in the invention may include a combination of antigen, immune response enhancer and a suitable carrier or excipient (column 27). Probst et al teach that vaccines of the invention may also contain other *Chlamydia* antigens either incorporated into a combination polypeptide or present within a separate polypeptide (column 27). Probst et al teach SEQ ID NO :177 which is the predicted full-length amino acid sequence for *C. trachomatis* (column 10). Probst et al teach a

polypeptide (SEQ ID NO: 177) that is 98% identical to SEQ ID NO:2 and comprises the claimed peptide fragment of SEQ ID NO: 5. See enclosed sequence alignment.

Probst et al do not specifically teach the use of high molecular weight proteins *Chlamydia trachomatis*.

Murdin et al teach an attenuated poliovirus hybrid expressing a neutralization epitope from the major outer membrane protein of *Chlamydia trachomatis* as well as a 40kDa (high molecular weight) outer membrane protein of *Chlamydia trachomatis* (page 4406, column 2, paragraph 2), in an analogous art for the purpose of inducing a strong mucosal immune response in primates and humans (see the Abstract).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to add the poliovirus-chlamydia hybrid as taught by Murdin et al to the vaccine composition of Probst et al because Probst et al teach that vaccines of the invention may also contain other *Chlamydia* antigens either incorporated into a combination polypeptide or present within a separate polypeptide (column 27). Therefore, it would have been expected barring evidence to the contrary, that the addition of poliovirus-chlamydia hybrids to the vaccine composition of Probst et al would allow for a powerful subunit vaccine because Murdin et al teach that poliovirus infection induces a strong mucosal immune response in primates and humans which indicate that poliovirus-chlamydia hybrids could become a powerful tool for the development of chlamydial vaccines (see the Abstract).

Status of Claims

14. Claims 94 and 95 appear to be free of the cited prior art.

Conclusion

15. Any inquiry of the general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308–0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Office Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for the Group 1600 is (703) 308-4242.

Any inquiry concerning this communication from the examiner should be directed to Vanessa L. Ford, whose telephone number is (703) 308-4735. The examiner can normally be reached on Monday – Friday from 7:30 AM to 4:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (703) 308–3909.

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February 4, 2002

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